IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

KATHLEEN A. MARTIN, Plaintiff, v. MERCK & CO., INC., et al. Defendants.	CIVIL ACTION No.: 05CV11716 MLW

PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION TO STAY

Now comes Plaintiff, Kathleen Martin, and hereby opposes the Motion to Stay filed by the Defendant, Merck & Co., Inc. ("Merck") on August 30, 2005.

I. Introduction

Staying this motion would be an inefficient use of judicial resources and would unreasonably delay the simple threshold jurisdictional question raised by the Plaintiff's Motion to Remand. Staying this motion would be unduly prejudicial, unfair and unnecessarily costly to the Plaintiff.

Given the present situation in New Orleans, LA, the location of the Eastern District of Louisiana, a conditional transfer order by the Panel is by no means "inevitable" or even likely. According to the website of the Eastern District of Louisiana, the court is closed until further notice with all deadlines and delays suspended. Judge Fallon is about to move into temporary quarters in a Houston, Texas courthouse, where he cannot hold trial prior to the passage of appropriate legislation by congress (see *San Jose Mercury News*, online edition, Sept. 06, 2005: "Federal Vioxx cases removed to Houston due to Kathrina").

It would be unreasonable to require Plaintiff to wait until the situation in Houston has stabilized and until the US District Court for the Eastern District of Louisiana finally will be able to continue its work, only to obtain a resolution of a very straight-forward jurisdictional question that this court is well capable of resolving.

The pending Motion to Remand presents factual issues unique to this litigation and does not involve general questions of law or fact common to other cases before the transferee court *In Re VIOX Products Liability Litig, MDL – 1657*. Merck's removal action from state court is based solely on the allegation that the non-diverse healthcare defendants (Brigham Women's Hospital and Dr. Peter Millet) are fraudulently joined[1][1]. Consequently, the inquiry of the court with regard to the Motion to Remand will be limited to the question whether, taking all contentions made by the Plaintiff as true and resolving all uncertainties in favor of Plaintiff, Merck can safely establish that there is no reasonable basis for any of the plaintiffs claims against the healthcare defendants. This involves an analysis of the factual allegations made in this case, with reference to Massachusetts law.

The Motion to Remand, including the support memorandum, has already been filed. It would be entirely appropriate and reasonable for this court to decide the pending Motion to Remand, as it relates to the simple, case specific, factual question regarding the validity of Plaintiff's claims against the non-diverse defendants. Staying this motion would, as shown above, create hardships and delays for Plaintiff whereas a denial would not create any visible hardship or prejudice to Defendant.

Therefore, Plaintiff respectfully submits, that this court exercise its discretion to deny Defendant's motion to stay and hear and decide Plaintiff's Motion to Remand.

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[1] Plaintiff's counsel has been advised by Defendant Pinto-Powell and Carr's counsel that those defendants did not consent to removal and that removal may be challenged by them.

II. Procedural History

Plaintiff filed a Complaint and Jury Demand in this matter on April 19, 2004, in Essex Superior Court, Massachusetts, and served the complaint upon Defendant Merck on July 20, 2004. On August 5, 2005, Defendant Merck filed an answer.On August 18, 2005, Defendant Merck removed this action to the United States Federal District Court for the District of Massachusetts. The sole ground raised by Merck regarding the existence of federal jurisdiction was its factually unsupported contention that the joinder of the (partly non-diverse) healthcare defendants was fraudulent. Plaintiff moved to remand this action to the Essex Superior Court on August 29, 2005 and Defendant Merck moved the US District Court to stay all proceedings pending the alleged transfer decision by the Judicial Panel on Multidistrict Litigation on August 30, 2005.

III. Argument

As recently decided by the United States District Court for the District of Michigan, the entry of a conditional transfer order *"does not affect or suspend orders and pretrial proceedings in the district court in which the action is pending and does not in any way limit the pretrial jurisdiction of that court". Johnson v. Micron Technology, Inc. 345 F. Supp. 2nd 736, 739 (ED Mich. 205).*

The case at bar was not even yet subject to a transfer order, Defendant Merck expects that the case might be subject to a conditional transfer order in the future, based on an alleged likeness with the standard VIOXX case.

In *State of Sao Paolo v. American Tobacco Company, Inc., 2000 US Dist. LEXIS 9617 (E.D. of Louisiana May 26, 2000)*, (unpublished), the court noted that there is:

... a preference that transferor courts consider, not stay, pending motions to remand, to avoid the

judicial inefficiency and delay incurred when cases which will ultimately be remanded to state court are centralized for a period before the transferee judge. Such reasoning is

consistent with the jurisprudence which requires district courts to consider jurisdiction as a threshold issue".

It would be highly inefficient to stay any procedural determination in order to await a transfer order that might or might not be issued, and then await the possible transfer of the case to the Louisiana Court, temporarily quartered in Houston, Texas, only to see it remanded to Essex Superior Court after the New Orleans/Houston court resolved the simple, straightforward question of whether or not certain defendants were properly joined under Massachusetts law. These considerations carry even more weight when the current situation in New Orleans, LA, is taken into account. This court is capable to resolve this question and can do so much faster and more efficiently than elsewhere.

The Complaint and Amended Complaint specifically allege with regard to the non-diverse defendants Peter Millet, M.D. and Brigham Women's Hospital that those defendants were aware of the combination treatment of Plaintiff with Vioxx, aspirin and vitamin E and participated in the prescription of drugs that had known contraindications with Vioxx[2][2]. They negligently breached the standard of due medical care, hence committing medical malpractice against Plaintiff. As stated in Exhibit A (medical opinion of Dr. Goldhaber of Brigham Women's Hospital hereto), the near fatal bleedings Plaintiff suffered were "most likely due to the combination of Vioxx, aspirin and Vitamin E", a treatment that was monitored by Dr. Millet at Brigham Women's Hospital.

Plaintiff's request that this court consider and decide the Motion to Remand, which would only require a threshold review of Plaintiff's claim against the non-diverse defendants and such a determination will have no effect whatsoever on issues that might be common to other Vioxx cases pending in MDL – 1657.

In *Hanan v. Ford Motor Company, 2003 U.S. Dist. Lexis (N.D. Cal. August 4, 2003)* the court noted that

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[2] On August 29, 2005, the First Amended Complaint was served with a Motion to Amend upon Defendant Brigham and Women's counsel to be filed with Defendant's Motion to Dismiss in accordance with Massachusetts Superior Court Rule 9A, under which same was served. This Rule 9A submission has not yet been filed with this Court. Plaintiff will move to amend its Complaint after a jurisdictional determination is made. Attached as Exhibit B hereto is a copy of the proposed First Amended Complaint.

"it is best to resolve promptly the question of federal subject-matter jurisdiction so that this case may proceed in the appropriate forum without delay". In *Nicholas v. Prudential, 1997 U.S. Dist. Lexis (S.D. Ala. April 28, 1997)* the court noted that a transfer to an MDL proceeding *"unnecessarily burdens the plaintiffs right to proceed in the forum of their choosing".*

And in *Aetna U.S. Healthcare, Inc. v. Hoechst Aktiengesellschaft, et all, 54 F. Supp. 2s 1042*, 1047, the court observed:

"The Court sees no reason to delay ruling on plaintiffs' motion to remand ... While staying the proceedings might allow a single district court to rule on the jurisdictional issue in the various cases, a stay would not affect the law that applies to the present case and little would be gained by a stay of decision on the motion to remand. The parties would still be subject to Kansas law. No great judicial economy will be realized from a delay. The parties will not save time, for they have already briefed the remand issue. The Court is well versed in both Kansas and federal law, while the transferor court would need to apply the law of different states to different claims...For purposes of judicial economy, the jurisdictional issue should be resolved immediately. If federal jurisdiction does not exist, the case can be remanded before federal resources are further expended. In the Court's view, judicial economy dictates a present ruling on the remand issue."

It should further be noted that in a simliar litigation, Linder Isner as Executrix of the Estate of Jeffrey Isner, M.D v. Merck & Co. Inc. at all, Civil Action No. 05-10328.DPW, this court denied a motion to stay filed by Merck, based upon the same legal arguments. The case was ultimately remanded to state court.

III. Conclusion

For the reasons set forth above, Plaintiff requests that this Court deny Defendant's Motion to Stay and decide the Motion to Remand.

Respectfully Submitted,

Andrew J. Tine
BBO#633639
Haese, LLC
30 Federal Street, 3rd Floor
Boston, MA 02110
Tel. (617) 428-0266
Fax (617) 428-0276

CERTIFICATE OF SERVICE

I, Andrew J. Tine, herby certify that I served the foregoing Plaintiff's Opposition to Defendant's Motion to Stay upon Foley Hoag LLP, Ficksman & Conley, LLP, and Martin Magnuson McCarthy & Kenney, at their last known addresses, via U.S. Mail, postage paid, this 13th day of September 2005.

BRIGHAM AND WOMEN'S HOSPITAL
HARVARD TEACHING AFFILIATE
BOSTON, MASSACHUSETTS 02115

187-03-35-5

MARTIN, KATHLEEN

EXHIBIT A

BRIGHAM MEDICAL SPECIALTIES

Note on 08/31/04
Regarding: Note

NOTE:

August 31, 2004
Wolfgang Fitz, M.D.
Department of Orthopedic Surgery
Brigham and Women's Hospital
75 Francis St
Boston, MA 02115
RE: Kathleen Martin
MR #187-03-35-5
Dear Wolfgang:
Thank you for your kind referral of Kathleen Martin, 57 years old, who has a history of postoperative deep vein thrombosis in 2002 following prior left knee surgery. As you know, she was hospitalized in March of 2004 with a major GI bleed requiring a transfusion of 12 units of packed red blood cells. At the time, she was taking full strength aspirin, Vioxx, and vitamin E. Since then, she has not taken any of these and despite a flare of her diverticulitis, over the last week, her hematocrit has remained stable and has had no further evidence of GI bleeding.
In addition to her history of deep vein thrombosis in June of 2002 following a left ACL repair, she has a history of hypertension, osteoarthritis, diverticulitis and multiple sclerosis which was diagnosed at the age of 23.
She has also undergone a fibroid embolization in 2000 and following that an umbilical hernia repair.
She has no family history of clotting disorders.
She is currently unemployed but has her PHD in child psychology. She has two children.
She does not smoke but she does enjoy a glass of wine each day.
She currently has no symptoms of chest pain, shortness of breath or leg pain. The remainder of her review of systems is negative.
Martin, Kathleen
MR #187-03-35-5 -2- August 31, 2004
Her current medications include Tegretol 200 mg daily, an Estraderm patch, glucosamine chondroitin and Lopressor daily.
On physical examination, she is healthy appearing. Weight 159 pounds, blood pressure 140/90 mmHg, heart rate 72 and regular, respirations 16 per minute. HEENT is normal.
Neck has no jugular vein distention. Chest is clear to auscultation bilaterally. Heart is regular rhythm with a normal S1, single S2 and no murmur, rub or gallop. Abdomen has no mass or hepatomegaly. Extremities have no clubbing, cyanosis or edema and the skin has no rash.
Kathleen Martin is stable from a cardiovascular standpoint. I do think that it

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187-03-35-5

MARTIN,KATHLEEN

EXHIBIT A

--NOTES-- (continued)

would be
safe for her to be prophylaxed with Coumadin following knee replacement surgery. Her
prior GI bleeding was most likely due to the combination of Vioxx, aspirin and vitamin E
and since she is no longer taking these, she should do well.
Thank you for letting me work with you to take care of this kind woman.
Best personal regards.
Sincerely yours,
Samuel Z. Goldhaber, M.D.
Erin Glasheen, PA-C
Scribe for Samuel Z. Goldhaber, M.D.
/db
******** Not reviewed by Attending Physician ********

Note by GOLDHABER,SAMUEL ZACHARY,M.D. (SG4)

COMMONWEALTH OF MASSACHUSETTS

ESSEX, ss

SUPERIOR COURT
CIVIL ACTION NO.: 2005-00641-D

KATHLEEN A. MARTIN,
Plaintiff,

v.

MERCK & CO., INC., DARTMOUTH -HITCHCOCK MEDICAL CENTER, DR. ROSHINI PINTO POWELL, DR. CHARLES CARR, BRIGHAM AND WOMEN'S HOSPITAL and DR. PETER J. MILLETT,
Defendants.

FIRST AMENDED COMPLAINT AND JURY DEMAND

This is an action brought by Plaintiff for damages resulting from the ingestion of the non-steroidal, anti-inflammatory pain medication called Vioxx (chemical name "rofecoxib"). This action seeks damages and the establishment of a medical monitoring program on behalf of the Plaintiff for the diagnosis and treatment of Vioxx-related adverse health effects from which Plaintiff presently suffers. This action is also brought based on the actions or inactions of the Dartmouth-Hitchcock Medical Center and Brigham and Women's Hospital in allowing the drug to be prescribed to Plaintiff as well as the specific actions of Dr. Charles Carr, Dr. Roshini-Pinto Powell and Dr. Peter J. Millet in prescribing the medication and/or failing to provide the proper treatment to Plaintiff.

I. INTRODUCTION

1. Plaintiff Kathleen A. Martin ("Martin") brings this civil action for damages and medical monitoring as a result of harm suffered from (a) the purchase and use of Vioxx;

EXHIBIT B

(b) the increased risk of health problems causally connected to the consumption of Vioxx; and (c) the actual health problems already experienced by Plaintiff as a result of the consumption of Vioxx.

2. Plaintiff purchased Vioxx and ingested the drug on a regular basis, as prescribed by her physicians, Dr. Roshini Pinto-Powell, Dr. Charles Carr, and Dr. Peter Millet. At all times relevant hereto, Defendants Dr. Roshini Pinto-Powell and Defendant Dr. Charles Carr were employed and/or otherwise affiliated with the Defendant Dartmouth-Hitchcock Medical Center. At all relevant times hereto, Defendant Dr. Peter Millet was employed and/or otherwise affiliated with the Defendant Brigham and Women's Hopsital.

3. Ingestion of Vioxx has been linked to an increased risk of adverse health effects for users, including the increased risk of cardiovascular events such as heart attack, stroke, and risk of GI bleeding.

4. The Food and Drug Administration ("FDA") approved Vioxx in 1999 for the reduction of pain and inflammation caused by osteoarthritis, as well as for acute pain in adults and for the treatment of menstrual pain. The FDA accelerated the approval process of Vioxx because of a perceived benefit to consumers over the available alternatives at the time, including ibuprofen and naproxen. Subsequently, the FDA approved Vioxx to treat the signs and symptoms of rheumatoid arthritis in adults and children.

5. In June 2000, Merck & Co. Inc. ("Merck") submitted to the FDA a safety study called VIGOR (Vioxx Gastrointestinal Outcomes Research) that found an increased risk of serious cardiovascular events including heart attacks and strokes, in patients taking

Vioxx compared to patients taking naproxen. Defendant Merck attributed these results to a purported "cardio-protective effect" of naproxen.

6. Despite reports over the next few years to the contrary, Defendant Merck continued to maintain that Vioxx did not increase a user's risk of cardiovascular events such as heart attack and stroke.

7. On September 30, 2004, Defendant Merck revealed that Vioxx doubled the risk of heart attack and stroke to consumers who took the drug for longer than 18 months, as compared to subjects taking a placebo. As a result of this revelation, Vioxx was withdrawn from the market worldwide.

8. However, the withdrawal from the market came after Plaintiff Kathleen A. Martin ingested the drug without notice of the inherent risks to her health. As such, Plaintiff suffered harm in that her consumer choice was distorted by misleading representations by Defendant Merck, and now Plaintiff is at increased risk of cardiovascular events, such as heart attack and stroke, and thrombosis, hemorrhage, and drainage to GI track, and thus requires medical monitoring.

II. PARTIES

9. Plaintiff Kathleen A. Martin is currently a resident of the Commonwealth of Massachusetts and acquired and ingested Vioxx while first a resident of Vermont and later of Rockport, Massachusetts.

10. Defendant Merck & Co., Inc. describes itself as a global research-driven pharmaceutical company which discovers, develops, manufactures and markets a broad range of products to improve human and animal health, directly and through joint ventures. Merck is incorporated under the laws of the State of New Jersey with its

principal place of business at One Merck Drive, Whitehouse Station, New Jersey. Defendant was in the business of profiting from the design, manufacture, marketing, distribution and/or sales of the brand-name prescription drug Vioxx.

11. Defendant Dartmouth Hitchcok Medical Center is a patient treatment medical facility organized under the law of the State of New Hampshire with its principal place of business located at One Medical Center Drive, Lebanon, New Hampshire ("Dartmouth").

12. Defendant Brigham and Women's Hospital is a medical facility organized under the laws of the Commonwealth of Massachusetts with its principal place of business located at 75 Francis Street, Boston, Massachusetts.

13. Defendants Dr. Roshini-Pinto Powell and Dr. Charles Carr are medical doctors affiliated with and practicing under the auspices of the Defendant Dartmouth-Hitchcock Medical Center, both with business addresses of One Medical Drive, Lebanon, New Hampshire.

14. Defendant Dr. Peter Millet is a medical doctor affiliated with and practicing under the auspices of the Defendant Brigham and Women's Hospital, with a business address of 75 Francis Street, Boston, Massachusetts.

III. FACTUAL BACKGROUND

15. At all times relevant, Defendant Merck, itself or by use of others, did distribute, market, sell, promote, advertise, and otherwise distribute in the Commonwealth of Massachusetts, the pharmaceutical product Vioxx.

16. Vioxx belongs to a class of drugs called "non-steroidal anti-inflammatory drugs," or "NSAIDs." NSAIDs reduce pain by blocking the body's production of enzymes called cyclooxygenase, or "COX." of which there are two forms: COX-1 and

COX-2. Most traditional NSAIDs (such as ibuprofen and naproxen) work by blocking the COX-1 enzyme, which reduces pain but may lead to gastroinstestinal perforations and bleeds.

17. Vioxx, it is believed, blocks the COX-2 enzyme that triggers pain and inflammation while sparing the COX-1 enzyme that helps maintain normal stomach lining. It is indicated for treating the signs and symptoms of osteoarthirtis and rheumatoid arthritis, management of acute pain in adults, and treatment of primary dysmenorrhea.

18. Vioxx did not promise to be any more effective than traditional NSAIDs, like ibuprofen and naproxen, at treating inflammation and pain. The sole advantage of Vioxx over other NSAIDs was its purported improved safety profile.

19. Vioxx is a brand name used by Merck to market and distribute rofecoxib. Vioxx was approved for marketing based on information in the New Drug Application submitted by Merck to the FDA. The FDA put Vioxx on a fast-track approval process that lasted approximately 6 months. Merck obtained FDA approval on Vioxx in or around May of 1999 and began its distribution and sale throughout the United States, including Massachusetts, in or about May of 1999.

20. Merck concealed the serious cardiovascular risks associated with Vioxx because a successful launch of Vioxx was viewed as critical for Merck and safety concerns over hypertension, edema and/or cardiovascular events would have drastically impacted positioning in the market as compared to the competing drug, Celebrex (clecoxib), which was placed into the market by Merck competitors Pharmacia and Pfizer some three months prior to the launch of Vioxx.

21. Merck knowingly chose to place these adverse health risks on its consumers despite its knowledge at product launch and in post-marketing data thereafter that use of Vioxx carried significant risk factors. These adverse effects were realized in adverse event reports, in clinical trials adjudicated by primary investigators with Merck's assistance, and in one or more studies shortly after market launch, which showed statistically significant increases in adverse cardiovascular events among Vioxx users.

22. On or about December 16, 1999, the FDA called Merck to task for its materially false and misleading marketing and promotional materials. The FDA sent Merck an official letter (the "First FDA Warning Letter") admonishing it that the "promotion pieces.. .that promoted VIOXX (rofecoxib) ... are false and misleading because they contain misrepresentations of VIOXX's safety profile, unsubstantiated comparative claims, and are lacking in fair balance."

23. In March 2000, Merck released the results of a Merck-sponsored VIGOR Study, which had begun in or around January of 1999. The VIGOR Study revealed, among other things, "significantly fewer heart attacks were observed in patients taking Naproxen (0 percent) compared to the group taking VIOXX 50 mg (0.5 percent) in this study. There was no difference in cardiovascular mortality between the group treated with VIOXX or Naproxen."

24. Merck attributed the difference in rates of cardiovascular events to the fact that riaproxen has "cardio-protective effects," and not to an increased risk of cardiovascular events attributable to Vioxx.

25. In designing the VIGOR Study, Merck took the exceptional step of including an "external Vascular Event Committee (VEC), containing three separate subspecialty committees (cardiac, cerebrovascular, and peripheral), [] for surveillance, monitoring, and adjudication of vascular events occurring in COX-2 inhibitor trials." According to a July 13, 2002 article that appeared in the British medical journal, *The Lancet*, Merck "apparently was aware of possible myocardial toxicity before the [VIGOR] trial, because it set in place a separate adjudication procedure to study the event."

26. While VIGOR did demonstrate that Vioxx reduced the incidence of serious gastrointestinal side effects as compared to naproxen, it did not demonstrate an improved safety profile for Vioxx. The VIGOR data revealed that:

a. Patients on Vioxx were five times more likely to suffer a heart attack as compared to patients on naproxen;

b. Patients on Vioxx were 2.3 times more likely to suffer serious cardiovascular disease (including heart attacks, ischemic stroke, unstable angina, and sudden unexplained death) as compared to patients on naproxen;

c. According to the FDA. [e]valuation of safety by routine parameters showed no advantage of [vioxx] rofecoxib over Naproxen; and

d Patients on Vioxx actually suffered *more* cases of serious disease (either gastrointestinal or cardiovascular) than did naproxen users (61 and 57 cases respectively).

27. In industry sponsored studies presented at the European United League Against Rheumatism (EULAR), an organization in which Merck is a member and corporate sponsor, in June of 2000, it was shown that Vioxx use resulted in a statistically

significant increase in hypertension and myocardial infarction. Merck denied these studies as to the hypertension problems in the official publication of the American Pharmaceutical Association, Pharmacy Today. (*Spin War Aside, Lessons Emerge From Cox-2 Trials*, August 2000, page 3).

28. Merck continued to deny the ill health effects associated with Vioxx while at the same time reaping the profits obtained through the non-disclosure. Merck engaged in a massive advertising and sampling program and gained continued increases in market share, which enhanced Merck's financial bottom line. The effect was a more than $2 billion profit for Merck in 2000 and a 23 percent market share.

29. Merck continued to withhold relevant data from the public throughout the Class Period. For example, in November of 2000, Merck caused the publication of a study in the New England Journal of Medicine and knowingly downplayed and/or withheld from this publication the severity of cardiovascular risks associated with Vioxx consumption over Naproxen consumption.

30. On February 8, 2001, Merck submitted the results of the VIGOR Study to the FDA Arthritis Advisory Committee as part of Merck's application to modify the prescribing information for Vioxx to reflect the Drug's purported gastrointestinal ("GI") benefits.

31. In considering the VIGOR Study results, however, the FDA Advisory Committee concluded (in February 2001) Vioxx has no safety advantage over the generic drug naproxen, a drug that sells for a fraction of the cost of Vioxx. According to the *FDA Advisory Committee Briefing Document, VIOXX Gastrointestinal Safety,* dated February 8, 2001: "[I]n the VIGOR Study the potential advantage of decreasing the risk of

complicated [GI side effects] was paralleled by the increased risk of developing cardiovascular thrombotic events."

32. According to a memo prepared by an Advisory Committee member, Lourdes Villalba, M.D., dated February 8, 2001, which discusses the "Overall Safety" of Vioxx, "the VIGOR Study found there were more overall deaths among Study participants taking Vioxx than those taking naproxen (22 and 15, respectively).

33. The VIGOR results showed that 50mg doses of Vioxx increased the risk of heart attacks and cardiovascular disease. Faced with this treat to the success of its new blockbuster drug, Defendant Merch offered an unfounded explanation for the negative cardiovascular findings of the VIGOR Study. Defendant Merck asserted that the dramatically increased risk of heart attacks in persons taking Vioxx 50mg was not due to Vioxx; rather, Defendant Merck claimed naproxen was cardio-protective and thus dramatically reduced the risk of heart attacks. Tellingly, the marketers of naproxen have never promoted their drug as being cardio-protective.

34. On August 22, 2001, the *Journal of the American Medical Association* ("JAMA") published an article authored by cardiologists Eric J. Topol and Steven E. Nessen of the Cleveland Clinic Foundation entitled "*Risk of cardiovascular Events Associated With Selective Cox-2 Inhibitors*," which reported the results of a study of Vioxx and Celebrex. The JAMA article reported the findings of the Cleveland Clinic's study that "current data would suggest that use of these so-called 'COX-2 inhibitors' might lead to increased cardiovascular events."

35. The day before the JAMA article was published, *Bloomberg News* reported that Merck commented, with regard to the article, "We have additional data beyond what they cite, and the findings are very, very reassuring. Vioxx does not result in any increase in cardiovascular events compared to placebo." Further, on August 23, 2001, the day after the article was published, Merck stated in a press release, "the Company stands behind the overall and cardiovascular safety profile...of Vioxx."

36. In a follow-up study reported in the Journal of the American College of Cardiology on or about February 6, 2002, Dr. Richard J. Bing conducted scientific testing and confirmed that the Cox-2 inhibitor tips the balance of prostacyclinlthromboxane in favor of thromboxane, leading to increased vascular and thrombotic events.

37. In September 2001, the FDA sent Defendant another warning letter (the "Second FDA Warning Letter") which again warned Defendant that Merck's marketing of VIOXX was "false, lacking in fair balance, or otherwise misleading..." The Second Warning Letter went on to advise Merck that Merck's marketing "minimize[s] the potential serious cardiovascular findings that were observed in the VIGOR Study. minimize[s] the VIOXX/Coumadin drug interaction, omit[s] crucial risk information associated with VIOXX therapy. contain[s] unsubstantiated comparative claims, and promote[s3 unapproved uses."

38. The Second Warning Letter also reprimanded Merck for:

> "assert[ing] that Vioxx does not increase the risk of [heart attacks] and that the VIGOR finding is consistent with naproxen's ability to block platelet aggregation like aspirin. That is a possible explanation, but you fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have pro-thrombotic properties."

39. Merck denied reports concerning the increased risk of cardiovascular problems as inaccurate and inconclusive. For example, on May 22, 2001, Merck issued a press release through the *PR Newswire* that stated, among other things: "In response to news and analyst reports of data the Company first released a year ago, Merck & Co., Inc. today reconfirmed the favorable cardiovascular safety profile of Vioxx."

40. The theory that naproxen had a cardioprotective effect and therefore accounted for the higher cardiovascular risks among Vioxx users was debunked in approximately January of 2002 by a Vanderbilt University School of Medicine human epidemiologic peer-reviewed study. The study was published in *The Lancet*, and concluded that there is an absence of a protective effect of naproxen or other non-aspirin non-steroidal anti-inflammatory drugs on risk of coronary heart disease. Ray, W., et. at., *Non-Steroidal Anti-Inflammatory Drugs and Risk of Serious Coronary Heart Disease: An Observational Cohort Study, The Lancet,* 359: 118-123, Jan. 12, 2002.

41. The FDA's Adverse Reporting System ("AERS") database is a computerized system for collecting and maintaining information about adverse events reported by drug manufacturers, health professionals, and others. The system contains adverse events detected and reported after marketing of the drug.

42. According to AERS, through October of 2003, almost 2,000 adverse cardiovascular events were experienced by persons taking Vioxx, including myocardial infarctions, cardiac arrests, and cardiac failures. These cardiac events reported to the FDA, which, according to some measures, represent underreporting of as much as 99%, resulted in such outcomes as hospitalization, life threatening conditions, and even death.

43. On October 22, 2003, *Reuters* published an article that stated "arthritis drug is suffering from clinical trial data suggesting it might slightly raise the risk of heart attacks, and the growing perception that its pain-fighting capabilities are no better than traditional painkillers."

44. On October 30, 2003, in an article entitled "Vioxx Study Sees Heart-Attack Risk," *The Wall Street Journal* reported that another study, sponsored by Merck, presented at the annual meeting of the American College of Rheumatology, confirmed an increased "risk of heart attacks in patients taking the pill [Vioxx]." According to *The Wall Street Journal* article, within the first 30 days of taking Vioxx, the risk of a heart attack was increased 39% as compared to Vioxx's competitor, Celebrex.

45. At all times relevant to this litigation, Defendant Merck had a significant market share based upon claims of Vioxx's efficacy, a very aggressive marketing program which involved financial incentives to sales teams, infusion of some 700 new sales representatives, and a massive advertising and sampling program.

46. If Merck had not engaged in this conduct, consumers, including Plaintiff, would have known the true risks of ingesting Vioxx and would have switched from Vioxx to safer products or refrained wholly from its use.

47. The marketing strategies of the Merck targeted Plaintiff and the other users to induce them to purchase Vioxx. At the time the Merck distributed, manufactured and marketed Vioxx, Merck intended that Plaintiff would rely on the marketing, advertisements and product information propounded by Merck, as well as Merck's omission of relevant negative information from such materials.

48. From the initial marketing of Vioxx until April 2002, the safety label for Vioxx set forth an explicit warning concerning "Gastrointestinal (GI) Effects." Specifically, the safety label warned of the "Risk of GI Ulceration, Bleeding, and Perforation." Nowhere within the safety label did Merck make full or adequate disclosure of the cardiovascular safety issues related to Vioxx.

49. After reviewing the results of the VIGOR study and other available data from controlled clinical trials, the FDA consulted with its Arthritis Advisory Committee. In April 2002, pursuant to the review by the FDA and resultant instructions, Merck implemented labeling changes for Vioxx to reflect the findings from the VIGOR study. The labeling changes included information about the occurrence of cardiovascular events, including heart attack and stroke, in some patients. At no time did the safety label disclose the level of risk that consumers were subjected to as a result of their ingestion of Vioxx. In fact, Merck continued to stand by the "safety profile" of Vioxx.

50. The April 2002 labeling changes were insufficient to put the consuming public on notice of the extent of the risk of adverse health effects that use of Vioxx presented.

51. Thus, despite knowledge in its clinical trials and post-marketing reports, studies and information relating to cardiovascular-related adverse health effects, Merck promoted and marketed Vioxx as safe and effective for persons such as Plaintiff.

52. Merck failed to reveal the true connection between use of Vioxx and cardiovascular events until September 30, 2004.

53. On or about June 2, 2002, Plaintiff Martin underwent surgery at the Dartmouth-Hitchcock Medical Center to repair the left anterior cruciate ligament tear in her left leg; the surgical procedure being performed under the care of Dr. Charles F. Carr, MD.

54. On or December 19, 2002, Martin was prescribed Vioxx by Dr. Roshini Pinto-Powell, M.D. of the Dartmouth-Hitchcock Medical Center.

55. Dr. Powell, Dr. Carr and the Dartmouth-Hitchcock Medical center knew or should have known of the dangers and contraindications posed by the prescription to and subsequent use by Plaintiff Martin of the drug Vioxx, but prescribed the drug without regard thereto.

56. On or about October 8, 2002, Dr. Powell recommended that Martin take Alleve for pain in combination with Vioxx.

57. Martin was treated by Dr. Millett at Brigham and Womem's Hospital during the summer and fall of 2003.

58. Dr. Millett prescribed Vioxx to Martin and recommended that she also take aspirin for pain.

59. At the time the defendant physicians prescribed Vioxx in combination with aspirin and other pain reducers, the defendants knew or should have known of the dangers and contraindications associated with same.

60. Martin continued to take the prescribed Vioxx and aspirin through and including March of 2004.

61. On or about March 10, 2004, Martin experienced severe bleeding and hemorrhaging, and was admitted to Massachusetts General Hospital, on an outpatient basis, and then sent home on an out-patient basis.

62. On or about March 11, 2004, Martin again experienced major gastrointestinal bleeding, was admitted again to Massachusetts General Hospital for emergency

treatment, said treatment requiring the transfusion of 12 units of packed red blood cells to deal with the blood loss and hemorrhaging.

63. On or about August 31, 2004, Dr. Samual Z. Goldhaber opined that Kathleen Martin's GI bleeding was most likely due to the combination of VIOXX, aspirin and vitamin E. Attached hereto as Exhibit A is a copy of Dr. Goldhaber's notes of August 31, 2004.

64. Martin continues to suffer serious and debilitating health conditions as a result of the use of the Vioxx prescribed, including but not limited to elevated risk of stroke, elevated blood pressure, complications during two (2) different medical with respect to procedures in relation to Plaintiff's left knee, and other cardiac issues.

COUNT I

(Misrepresentation - Merck)

65. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

66. Defendant Merck intentionally employed deceptive representations as to the risks and side effects of Vioxx in the marketing, promotion and sale of the drug to consumers, as set forth above.

67. Defendant Merck's wrongful conduct included the issuance of the false and misleading representations and omissions of material facts regarding Vioxx's capabilities and the side effects of Vioxx upon which Plaintiff relied.

68. Defendant Merck failed to sell Vioxx in the manner and of the nature advertised or offered, and was unable to provide Vioxx in accordance with other terms or conditions.

69. The fraudulent practices of Defendant Merck have directly, foreseeably, and proximately caused damages and injury to Plaintiff.

70. Defendants Merck's conduct, in part, caused Plaintiff to acquire and ingest Vioxx.

71. By reason of Defendant Merck's unlawful conduct, Plaintiff has suffered losses and is entitled to damages.

COUNT II

(Products Liability - Merck)

72. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

73. Merck had a duty to exercise reasonable care in the development, in providing adequate warnings, and to test Vioxx so as to prevent injury to foreseeable users.

74. Merck breached its duty to Martin by failing to develop a safe product and/or warn Martin of the known or reasonably foreseeable harms associated with ingesting Vioxx.

75. Merck failed to properly test or properly disclose or accurately report test results sot that foreseeable users could properly assess and/or be warned of the dangers or potential dangers associated with ingesting Vioxx.

76. Vioxx is unreasonably dangerous.

77. Martin suffered injury as a result of Merck's negligence and breach of warranty.

COUNT III

(Unjust Enrichment - Merck)

78. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth

herein.

79. As a direct proximate, and foreseeable result of Defendant Merck's acts and otherwise wrongful conduct, Plaintiff was economically harmed. Defendant Merck profited and benefited from the sale of Vioxx, even as Plaintiff suffered the noted harm.

80. Defendant Merck has voluntarily accepted and retained these profits and benefits, derived from Plaintiff with full knowledge and awareness that, as a result of Defendant Merck's unconscionable and intentional wrongdoing, Plaintiff, was not receiving products of the quality, nature, fitness, or value that had been represented by Defendant Merck or that a reasonable consumer would have expected. Plaintiff purchased medicine that she expected would improve her health, and instead found that her health was instead negatively affected.

81. By virtue of the conscious wrongdoing alleged in this Complaint, Defendant Merck has been unjustly enriched at the expense of Plaintiff, who is entitled to in equity, and hereby seeks, the disgorgement and restitution of Merck's wrongful profits, revenue, and benefits, to the extent, and in the amount, deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Merck's unjust enrichment.

COUNT IV

(Medical Malpractice - Defendants Pinto-Powell, Carr, Millett, Dartmouth Hitchcock Medical Center and Brigham and Women's Hospital)

82. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

83. Defendant Dr. Pinto-Powell and Dr. Charles Carr are medical doctors licensed to deliver medical services to the public at large within the State of New Hampshire.

84. At all relevant times, Defendant Millett was a medical doctor licensed to delivery medical services to the public at large within the Commonwealth of Massachusetts.

85. Plaintiff on multiple occasions was treated by Defendants Pinto-Powell, Defendant Carr and Defendant Millett.

86. The Defendant medical doctors were aware of the combination of drugs being prescribed to Plaintiff and/or participated in the prescription of VIOXX and/or drugs that had known contraindications with VIOXX.

87. Defendant Pinto-Powell, Defendant Carr and Defendant Millett breached the standard of medical care, or in other words, were negligent in the delivery of medical services and treatment as set forth above and thus breached the standard of due care and diligence in the medical treatment of the Plaintiff.

88. Martin has suffered injuries from the medical services and treatment received from Defendant Pinto-Powell, Defendant Carr, Defendant Millett and their respective employers.

89. Defendant Pinto-Powell, Defendant Carr, Defendant Millett and their respective employers acted negligently in providing medical services and treatment to Martin, resulting in damages and injuries to Martin.

COUNT V

(Breach of Contract - Defendant Dartmouth–Hitchcock Medical Center and Defendant Brigham and Women's Hospital)

90. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

91. Defendant Dartmouth and Brigham and Women's Hospital's entered into a contract with Plaintiff to provide professionally competent and reasonably adequate medical services.

92. Defendant Dartmouth and Brigham and Women's Hospital failed to provide medical services in a professional and reasonable manner in accordance with standard practices and requirements.

93. Defendant Dartmouth and Brigham and Women's Hospital failed to warn Plaintiff of the dangers of Vioxx, even though Defendant Dartmouth and Brigham and Women's Hospital and/or its medical professionals and staff knew or had reason to know of the dangers of Vioxx and thus failed to deliver the medical and supporting services in accordance with the agreement between the parties and/or in accordance with standard medical practice.

94. Defendant Dartmouth and Brigham and Women's Hospital failed to warn Plaintiff of the dangers of Vioxx, even though Defendant Dartmouth and/or its medical professionals and staff knew or had reason to know of the dangers of Vioxx.

95. Defendant Dartmouth and Brigham and Women's Hospital breached the respective contracts with Plaintiff Martin resulting in substantial injury, harm and damages to Plaintiff Martin.

COUNT VI

(Unjust Enrichment - Defendant Dartmouth-Hitchcock Medical Center and Brigham and Women's Hospital)

96. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

97. As a direct proximate, and foreseeable result of Defendant Dartmouth-Hitchcock Medical Center's and Brigham and Women's Hospital's acts and otherwise wrongful conduct, Plaintiff was economically harmed. Defendant Dartmouth-Hitchcock Medical Center and Brigham and Women's Hospital profited and benefited from the sale of Vioxx, even as Plaintiff suffered this harm.

98. Defendant Dartmouth-Hitchcock Medical Center and Brigham and Women's Hospital has voluntarily accepted and retained these profits and benefits, derived from Plainitiff with full knowledge and awareness that, as a result of Defendants' unconscionable and intentional wrongdoing, Plaintiff was not receiving products of the quality, nature, fitness, or value that had been represented by Defendants or that a reasonable consumers, expected. Plaintiff purchased medicine that she expected would improve her health, and instead found her health negatively affected.

99. By virtue of the conscious wrongdoing alleged in this Complaint, Defendant Dartmouth and Brigham and Women's Hospital has been unjustly enriched at the expense of Plaintiff, who is entitled to in equity, and hereby seek, the disgorgement and restitution of Defendant's wrongful profits, revenue, and benefits, to the extent, and in the amount, deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows on each and every Count of its Complaint:

1. General damages in amount to be proven at trial and in excess of the jurisdictional minimum of this Court;

2. Pre-judgment and post-judgment interest as provided by law;

3. Full refund of all purchase costs Plaintiff paid for Vioxx;

4. Compensatory damages in excess of the jurisdictional minimum of the Court, according to proof;

5. Consequential damages in excess of the jurisdictional minimum of the Court, according to proof;

6. Disgorgement of all profits associated with Vioxx;

7. Injunction requiring Defendant to fund a medical monitoring program to address the needs of the Plaintiff associated with the use of Vioxx; and

8. Such further relief as this Court deems necessary, just and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY ON ALL COUNTS AND ISSUES SO TRIABLE

Plaintiff,
By her attorneys,

Andrew J. Tine
BBO#633639
Haese, LLC
30 Federal Street, 3rd Floor
Boston, MA 02110
Tel. (617) 428-0266
Fax (617) 428-0276